



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

Purged

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**WARNING LETTER
NWE-08-01W**

January 19, 2001

VIA FEDERAL EXPRESS

Robert Hawthorne, President
Ocean Spray Cranberries, Inc.
One Ocean Spray Drive
Lakeville-Middleboro, Massachusetts 02349

Dear Mr. Hawthorne:

The Food and Drug Administration (FDA) reviewed your firm's internet labeling for your Ocean Spray juice products. The container label for your grapefruit juice products directs the consumer to your website via the statement "For grapefruit health facts visit: www.oceanspraygrapefruit.com." The container labels for your other Ocean Spray juice products also bear your internet website address "www.oceanspray.com." We have concluded that the labeling found on your internet sites causes your Ocean Spray juice products to be in violation of the Federal Food, Drug, and Cosmetic Act [the Act], and Title 21, Code of Federal Regulations [21 CFR].

Your Cran-Health, Grapefruit Health, Press Releases and Juice Nutrition 101 internet sites and related links contain unauthorized health claims. Unauthorized health claims in the labeling of foods cause the products to be misbranded under section 403(r)(1)(B) of the Act. The following are examples of some of the unauthorized health claims found on the website links listed above:

"Vitamin C in its 100% juice line...associated with a reduced risk of chronic diseases such as cancer, cardiovascular disease and cataracts," "Beta-carotene...is a powerful antioxidant...associated with a reduced risk of some cancers. Both the Surgeon General's Report and the National Research Council's Report concluded that eating plenty of foods high in beta-carotene may protect against some epithelial cancers," "...citrus fruits may protect against non-hormone dependent cancers," "Flavonoids...reduce intravascular blood clotting...stroke prevention," "...cranberries may also prevent certain harmful bacteria in the mouth from sticking to the teeth...bacteria are associated with

periodontal gum disease," "Cranberry juice cocktail significantly inhibited the E. coli bacteria, which cause 80 to 90 percent of UTIs, from adhering to the urinary tract," "preliminary research indicates that the unique antioxidant compounds found in raspberries and grapes reduce the risk of cancer and heart disease," "Vitamin C...helps prevent hemorrhaging...and helps prevent viral infections such as the common cold..." and "drinking one glass of grapefruit juice every day reduced the risk of stroke by 25%."

Your Grapefruit Health and Cran-Health website links also contain other health claims that, as written, do not contain all the elements set forth in Title 21 Code of Federal Regulations [21 CFR] Part 101, Subpart E, for their respective health claims. Therefore, claims such as those listed below are also unauthorized health claims, which cause the products to be misbranded under section 403(r)(1)(B) of the Act:

"Folic acid...is important for pregnant women because it helps prevent certain birth defects" [21 CFR 101.79], "...grapefruit pectin (a soluble dietary fiber) may protect against heart disease by lowering blood cholesterol" [21 CFR 101.77], "Include pectin-rich foods like Ocean Spray fresh grapefruit as part of a low-fat,...prevention of heart disease" [21 CFR 101.77], "...American Heart Association...stamp of approval to all Ocean Spray Grapefruit juices and Ocean Spray fresh grapefruit...AHA's "heart check" food certification mark informs consumers these products are low in fat and cholesterol which reduces the risk of heart disease" [21 CFR 101.75], and "Cranberry Juice Cocktail PLUS...contributes to improved bone health, reduces the risk of osteoporosis..." [21 CFR 101.72].

Your internet sites also contain claims indicating that the products are intended to treat, cure or mitigate disease. Such claims are beyond the scope of the types of claims that are permitted on foods (e.g. structure/function claims or authorized health claims) and are evidence that the products are intended for use as drugs within the meaning of section 201(g) of the Act. The following are examples of such claims found on your websites:

"In cancer prone mice, resveratrol appeared to inhibit lesion development and reduce skin tumor occurrence...may help the body fight cancer...combating initial cellular and sub-cellular damage to halting or slowing tumor growth," "Research shows grapefruit juice slows breast cancer growth...", "In addition, incidence of the spread of tumors to the lungs and lymph nodes was markedly reduced in the cranberry-fed group," "...may help lower cholesterol in people with high blood cholesterol levels...", "...cranberry's importance as a promising therapeutic tool to help fight bacteria naturally," "...cranberry's anti-stick effect may fight H. pylori, the bacteria that are a cause of some stomach ulcers...", "Flavonoids...possess anti-inflammatory, anti-allergic, and/or anticarcinogenic activities ...," and "...as the issue of antibiotic resistance becomes more of a problem, drinking Ocean

Spray cranberry juice cocktail every day may be a valuable measure for maintaining urinary tract health.”

In addition, statements on your website under “Grapefruit Juice and Cancer Care,” pose a serious safety threat as they not only overstate any possible benefit associated with grapefruit juice consumption but also understate the very real risks associated with concomitant use of certain drugs and grapefruit juice. Your website states that grapefruit juice “enhances the absorption and effects of some medications.” This statement reflects the ability of grapefruit juice to block the metabolism of some drugs and, thereby, increase the blood levels of those drugs. The statement implies that the enhanced absorption and increased blood levels are a benefit. However, this statement may pose a serious risk for patients on certain medications.

The consumer would need to find a subsequent unnumbered footnote to receive a partial list of medications that may be affected by grapefruit juice and to receive a mild admonition to consult with a physician or pharmacist before taking the listed drugs. This presentation not only trivializes a serious risk, but also is likely to promote concomitant use of grapefruit juice and affected medications. Moreover, the site promotes grapefruit juice for the mitigation of diseases and conditions for which drugs are commonly prescribed that interact with grapefruit juice and for which warnings are appropriate. For example, the site claims that grapefruit juice can “lower cholesterol in people with high blood cholesterol levels,” but such patients may be taking cholesterol-lowering drugs, such as simvastatin, the labeling of which warns about the risk of grapefruit juice interaction.

The claims made for these products, as a legal matter, subject them to the requirements for new drugs [§201(p)] because there is no evidence that these products are generally recognized as safe and effective for their intended uses. Therefore, they may not be legally marketed in the United States without approved New Drug Applications [§505]. These products are also misbranded because your Ocean Spray juice products’ labeling fails to bear adequate directions for use [§502(f)(1)] and is false or misleading [§502(a)], as it suggests that the products are safe and effective for their intended uses when this has not been established.

This letter is not intended to be an all-inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the FDA without further notice. The Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be implemented. Your reply should be sent to the attention of Mr. E. Frank Gesing, Compliance Officer, at the above letterhead address.

Sincerely,

A handwritten signature in black ink, appearing to read "Gail T. Costello", with a long horizontal flourish extending to the right.

Gail T. Costello
District Director
New England District Office